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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,709	01/12/2001	David Bernard Fischer	P04814US0 PHI 1314	2738

27142 7590 11/14/2003

MCKEE, VOORHEES & SEASE, P.L.C.  
ATTN: PIONEER III-BRED  
801 GRAND AVENUE, SUITE 3200  
DES MOINES, IA 50309-2721

EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/759,709

Applicant(s)

FISCHER ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 12, 20, 21, 25, 33 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 20, 33, 41 and 42 is/are allowed.
- 6) ☒ Claim(s) 8, 12, 21, 25 and 43-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 July 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 12, 20-21, 25, 33, and 41-58 are pending. Applicant's amendments and arguments of 11 July 2003 have overcome the outstanding indefiniteness rejection except as indicated below, the new matter rejection, and the enablement rejection regarding a deposit of the parent lines.

Claims 8 and 21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated on page 2 of the last Office action.

Claim 58 (newly submitted) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 is indefinite in its recitation of "no statistically significant variation from 36N70", as it is unclear whether the variation is being measured on the basis of the expression of individual genes, the expression of particular traits, or the presence one or more traits.

Claims 8, 12, 21, 25 and 43-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 5 of the last Office action for claims 8-19, 21-32 and 34-40.

Claims 8, 12, 21, 25 and 43-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on page 5 of the last Office action for claims 8, 12-19, 21, 25-32 and 34-40.

The claims remain free of the prior art, as stated on page 5 of the last Office action.

Claims 1-7, 20, 33 and 41-42 are allowed.

Applicant's arguments filed 11 July 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the amendment to claims 8 and 21 obviates the outstanding indefiniteness rejection. The Examiner maintains that claims 8 and 21 are confusing for characterizing the male fertile plants of claim 2 and claim 20 as suddenly being male sterile.

Applicant urges that the claim amendments obviate the written description rejection, in view of the well-known nature of the backcrossing technique. The Examiner notes that claims 56 and 57 recite the broad genera of any gene whose proteinaceous or non-proteinaceous product somehow modifies fatty acid metabolism, starch metabolism, or phytate content. In contrast, the specification only provides guidance for particular individual genes within each of these genera. Unlike the other recited traits whose genera of genes conferring them have been well-characterized in the art, the latter three traits are the results of complex metabolic processes involving a multitude of enzymes, each encoded by a different gene. It is noted that Applicant has amended the claims in accordance with the Examiner's previous suggestions. Upon further review, it has been determined that further refinement of claim language was required in order to satisfy the written description requirement. The confusion is regretted.

Regarding backcrossing, the Examiner maintains that the knowledge of a particular breeding technique does not address the issue of the adequacy under 35 USC 112, first paragraph, of the written description of the plants involved in those techniques or produced by those techniques. While the backcross technique may be employed to introgress a particular gene into a recurrent parent and to obtain a plant which is substantially similar to the original recurrent parent, the specification fails to provide any characterization of the multitude of plants which exhibit some but not all of the collection of traits which render the exemplified hybrid patentable. See also Openshaw et al appended to the amendment of 11 July 2003, who teach that linkage

drag will interfere with successful introgressing of a desired trait while otherwise preserving the recurrent parent's genotype (page 43, column 1, bottom paragraph), and that at least four generations of crosses are needed to constitute more than 90% of the recurrent parent genome. The instant claims do not recite any number of generations of crosses. Thus, the claims read on plants with much fewer than 90% of the recurrent parent's genome, and with a substantial portion of the genome from a multitude of uncharacterized donor parents.

Applicant urges that the enablement rejection is improper, given the deposit of the hybrid and its parents, and the lack of a requirement to teach what is well known in the art, wherein one skilled in the art could evaluate the various traits of the plant products.

The Examiner maintains that the deposit of the parents or resultant hybrid does not address the enablement of claims drawn to a multitude of plants derived therefrom, produced by crossing with a multitude of undisclosed breeding partners. For transformation claims, the effect of increasing or decreasing the expression of an individual gene in complex metabolic pathways has not been well-characterized either by Applicant or the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

November 6, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

